

PTO/SB/08a (05-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/APTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 7

**Complete if Known**

Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned 1649
Examiner Name	Not Yet Assigned Hayes
Attorney Docket Number	ALLE0014-103 (17335CIP3)

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
RH	AA	US-6,458,365	10/01/2002	Aoki, et al	
	AB	US- 5,766,805	06/16/1998	Sanders et al	
	AC	US- 5,714,468	02/03/1998	Dao	
	AD	US- 6,464,988	10/15/2002	Aoki et al	
	AE	US- 6,113,915	09/05/2000	Aoki et al	
	AF	US- 6,308,403	10/23/2001	Donovan	
	AG	US- 6,299,893	10/09/2001	Schwartz et al	
	AH	US- 5,670,484	09/23/1997	Binder	
	AI	US- 6,423,319	07/23/2002	Brooks et al	
	AJ	US- 6,139,845	10/31/2000	Donovan	
	AK	US- 6,143,306	11/07/2000	Donovan	
	AL	US- 5,437,291	08/01/1995	Pasricha et al	
	AM	US- 6,365,164	04/02/2002	Schmidt	
	AN	US- 6,063,768	05/16/2000	First	
	AO	US- 6,395,277	05/28/2002	Graham	
	AP	US- 6,265,379	07/24/2001	Donovan	
	AQ	US- 6,358,513	03/19/2002	Voet et al	
	AR	US- 6,328,977	12/11/2001	Donovan	
	AS	US- 6,306,423	10/23/2001	Donovan	
	AT	US- 6,312,708	11/06/2001	Donovan	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
RH	BD	WO94/15629	07/21/94	AS Synapse Biol.		

Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete If Known</b>	
			Application Number	10/757,077
			Filing Date	January 14, 2004
			First Named Inventor	Lance E. Steward
			Art Unit	Not Yet Assigned
			Examiner Name	Not yet Assigned
Sheet	2	of 7	Attorney Docket Number	ALLE0014-103 (17355CIP3)

[illegible][illegible]

Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007
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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/757,077
		Filing Date	January 14, 2004
		First Named Inventor	Lance E. Steward
		Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	ALLE0014-103 (17355CIP3)
Sheet	3	of	7

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
RH	BE	ADENIS, et al., J. Fr. Ophthalmol. (1990) 13:259-284. (Abstract only in English)	
↓	BF	BINZ, et al., J. Biol. Chem. (1990) 265:9153-9158.	
	BG	BLITZER, et al., Ann. Otol. Rhinol. Laryngol. (1985) 94:591-594.	
	BH	BRIN, et al., Advances in Neurology, Vol. 50: Dystonia 2 (1988), pp. 599-608.	
	BI	CENGI DI BELLO, et al., Eur. J. Biochem. (1994) 219:161-169.	
	↓	BJ	COHN, et al., Neurology (1987) 37 (3 Supp. 1):123-124. (abstract only)
no copy in parent	BK	<del>DARROW, et al., J. Cell Biol. (1998) 442:819-822.</del>	
RH	BL	ELSTON, et al., Br. J. Ophthalmol. (1985) 69:718-724.	
↓	BM	<del>FAUCI, et al., Harrison's Principles of Internal Medicine, 14<sup>th</sup> ed., (1998) McGraw Hill</del> no copy	
	BN	ELSTON, et al., Br. J. Ophthalmol. (1985) 69:891-898.	
	↓	BO	GALLI, et al., Cell (1998) 9:1437-1448.

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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/757,077
		Filing Date	January 14, 2004
		First Named Inventor	Lance E. Steward
		Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
Sheet 4 of 7	Attorney Docket Number	ALLE0014-103 (17335CIP3)	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
RH	BP	JANCOVIC, et al., Neurology (1987) 37:618-623.	
no copies provided	BQ	<del>KADKHODAYAN, et al., Protein Expression Purif. (2000) 19:185-190.</del>	
	BR	KOZAKI, et al., J. Med. Biol. Biol. (1991) 34:51-55.	
	BS	<del>LAOY, et al., Nat. Struct. Biol. (1996) 3:660-662.</del>	
RH	BT	LI, et al., Biochemistry (1994) 33:7014-7020.	
↓	BU	MAISEY, et al., Eur. J. Biochem. (1988) 177:683-691.	
	BV	MARTINEZ-ARCA, et al., J. Cell Biol. (2000) 149:889-899.	
	BW	MILTON, et al., Biochemistry (1992) 31:8789-8809.	
	BX	MINTON, In Clostridial Neurotoxins: the molecular pathogenesis of tetanus and botulism, Montecucco, ed., Springer Verlag, NY, 1995, pp. 181-194.	
no copy	BY	<del>PEBEN, et al., J. Biol. Chem. (2001) 276:49160-49167.</del>	
RH	BZ	SWAIN, et al., Peptide Res. (1993) 6:147-154.	

Examiner Signature	/Robert Hayes/	Date Considered	01/03/2007
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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/757,077
		Filing Date	January 14, 2004
		First Named Inventor	Lance E. Steward
		Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	ALLE0014-103 (17355CIP3)
Sheet	5	of	7

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
RH	CA	ZHOu, et al., Biochemistry (1995) 34:15175-15181.	
	CB	SHIN, et al., J. Biol. Chem. (1991) 266:10658-10665.	
	CC	RASIBORSKA and CHARLTON, Can. J. Physiol. (1999) 77:679-688.	
	CD	ERDAL, et al., Arch. Pharmacol. (1995) 351:67-78.	
	CE	RAGONA, et al., The Larangyscope (1999) 109:1344-1346.	
	CF	NAUMANN, et al., Eur. J. Neurol. (1999) 6:S111-S115.	
	CG	KELLER, et al., FEBS Lett. (1999) 456:137-142.	
	CH	DIETRICH, et al., J. Cell. Biol. (1997) 138:271-281.	
	CI	GEISLER, et al., J. Biol. Chem. (1998) 273:21316-21323.	
	CJ	TAN, et al., J. Biol. Chem. (1998) 273:17351-17360.	
	CK	LIU, et al., Trends Cell Biol. (1999) 9:356-363.	

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 6 of 7

**Complete If Known**

Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
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RH	CL	CAI and SINGH, Biochemistry (2001) 40:4693.	
	CM	TIKKANEN, et al., Traffic (2000) 1:631-640.	
	CN	RAPAPORT, et al., EMBO J. (1998) 17:2148-2155.	
	CO	MIRANDA, et al., JBC Papers in Press (2001) 1-35.	
	CP	COWLES, et al., Cell (1997) 91:109-118.	
	CQ	AOKI, et al., J. Neurol. (2001) 248 (Supp 1):3-10.	
	CR	AOKI, Toxicol. (2001) 12:1815-1820.	
	CS	<del>"Protein Turnover and Autophagy," American Society for Cell Biology.</del> no date/ no page #s/ no yr	
	CT	WIEGAND, et al., Naunyn Schmiedberg's Arch. Pharmacol. (1976) 292:	
	CU	HABERMAN, Naunyn Schmiedberg's Arch. Pharmacol. (1974) 281:	
	CV	THOMPSON, et al., Eur. J. Biochem. (1990) 189:73.	

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	CW	<del>DI-95110, et al., Eur. J. Biochem. (1993) 210:161.</del> duplicate citation	
RH	CX	ARNON, et al., "Botulinum toxin as a biological weapon: medical and public health management," JAMA (2001) 285:1059-1070.	
	CY	ESWARAMOORTHY, et al., "A novel mechanism for Clostridium botulinum neurotoxin inhibition," Biochemistry (2002) 41:9795-9802.	
	CZ	AOKI, et al., "Is the light chain subcellular localization an important factor for Botulinum neurotoxin duration of action?," Naunyn Schmiedeberg Arch. Pharmacol. (2002) 365 (Suppl 2):R10.	
	DA	FERNANDEZ-SALAS, et al., "Localization of BoNT light chains in neuronal and non-neuronal cell lines, implications for the duration of action of the different serotypes," Naunyn Schmiedeberg Arch. Pharmacol. (2002) 365 (Suppl 2):R19.	
	DB	STEWART, et al., "BoNT/A light chain and the dileucine motif: potential implications for light chain localization and neurotoxin duration of action," Naunyn Schmiedeberg Arch. Pharmacol. (2002) 365 (Suppl 2):R44.	

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PTO/SB/08b(08-03)

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Sheet	1	of	1	Attorney Docket Number	ALLE0014-103 (17355 CIP3)

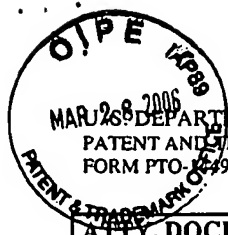
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RH	B1	FERNANDEZ-SALAS, et al., "Plasma Membrane Localization Signals in the Light Chain of Botulinum Neurotoxin," Slide presentation at USAMROD, January, 2004.	
↓	B2	FERNANDEZ-SALAS, et al., "Plasma membrane localization signals in the light chain of botulinum neurotoxin," Proc. Natl. Acad. Sci. USA (2004) 101:3208-3213.	
↓	B3	FERNANDEZ-SALAS, et al., "Is the light chain subcellular localization an important factor in Botulinum toxin duration of action?" Movement Disorders (2004) 19:S23-S34.	

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**LIST OF ART CITED BY APPLICANT**

ATTY. DOCKET: 17355-CIP3 (BOT)	SERIAL NO.: 10/757,077
APPLICANT: LANCE E. STEWARD, et al.	TITLE: CLOSTRIDIAL NEUROTOXIN COMPOSITIONS AND MODIFIED CLOSTRIDIAL NEUROTOXINS
FILING DATE: JANUARY 14, 2004	GROUP: 1649

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
RH	AA	2003/219462A1	11/27/2005	STEWART et al.	424	239.1	06/04/2002
RH	AB	2003/027752A1	02/06/2003	STEWART et al.	514	12	07/20/2001
	AC						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
RH	BA	WO 02/08268A2	01/31/2002	PCT	C07K	14/33	Y
	BB						

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

RH	CA	Fernandez-Salas, E., et al., <i>Plasma membrane localization signals in the light chain of botulinum neurotoxin serotype A</i> , Society for Neuroscience Abstract Viewer and Itinerary Planner, Vol. 2003; pages Abstract No. 9.2
	CB	Foran, Patrick G., et al., <i>Evaluation of the therapeutic usefulness of botulinum neurotoxin B, C1, E, and F compared with the long lasting type A. Basis for distinct durations of inhibition of exocytosis in central neurons</i> , Journal of Biological Chemistry, Vol. 278, No. 2, 10 January 2003, pp. 1363-1371
	CC	Wang Xingmin, et al., <i>Genetic analysis of type E botulinum toxin-producing Clostridium butyricum strains</i> , Applied and Environmental Microbiology, vol. 66, no. 11, November 2000, pp. 4992-4997
	CD	Fernandez-Salas, E., et al., <i>Plasma membrane localization signals in the light chain of botulinum neurotoxin</i> , Proceedings of the National Academy of Sciences of the United States of America, 2 March 2004, vol. 101, no. 9, pp. 3208-3213
	CE	
	CF	
	CG	

EXAMINER /Robert Hayes/ DATE CONSIDERED 01/03/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.